K021089

JUN 19 2002

tyco Healthcare

Nellcor

4280 Hacienda Drive
Pleasanton, CA 94588

Tele: 925 463-4000
Fax: 925 463-4020

510(k) Summary

Submitted by:	Nellcor Puritan Bennett Incorporated (A business unit of Mallinckrodt Inc., a division of Tyco Healthcare Group LP) 4280 Hacienda Drive Pleasanton, CA 94588
Company Contact:	Gina To Senior Regulatory Affairs Project Manager (925) 463-4427 (925) 463-4020 – FAX
Date Summary Prepared:	April 3, 2002
Trade Name:	OxiMAX MAX-FAST Adhesive Forehead Sensor
Common/Usual Name:	Oxygen Sensor
Classification Name:	Patient Transducer and Electrode Cable (including connector) (74DSA) (per 21 CFR §870.2900)
Substantially Equivalent Devices:	Nellcor Puritan Bennett, Incorporated OxiMAX Pulse Oximetry System with N-595 Pulse Oximeter and OxiMAX Sensors 510(k) #K012891

DEVICE DESCRIPTION

The OxiMAX MAX-FAST Adhesive Forehead Sensor is a disposable adhesive sensor for the forehead. MAX-FAST may be used on mechanically ventilated patients and on patients in supine position. MAX-FAST may be used continuously up to two days with appropriate site inspections, and will allow a maximum of four site changes and/or inspections with the removal of adhesive layers.

The OxiMAX MAX-FAST sensor contains a memory chip carrying information about the sensor which the oximeter needs for correct operation.

The OxiMAX MAX-FAST adhesive forehead sensor was cleared as part of the OxiMAX Pulse Oximetry System (510(k) #K012891). This forehead sensor was labeled for adults. The labeling has been updated to add pediatric use.

INTENDED USE

The Nellcor OxiMAX adhesive forehead reflectance sensor, model MAX-FAST, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for adult or pediatric (≥ 10 kg) patients.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE LEGALLY MARKETED (UNMODIFIED) DEVICE

No design modifications have been made to the OxiMAX MAX-FAST adhesive forehead sensor. Only labeling has been revised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2002

Nellcor Puritan Bennett, Inc.
c/o Ms. Gina To
4280 Hacienda Drive
Pleasanton, CA 94588

Re: K021089
OxiMAX MAX-FAST Adhesive Forehead Sensor
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: April 3, 2002
Received: April 4, 2002

Dear Ms. To:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021089

Device Name: OxiMAX MAX-FAST Adhesive Forehead Sensor

Indications For Use:

The Nellcor OxiMAX adhesive forehead reflectance sensor, model MAX-FAST, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for adult or pediatric (≥ 10 kg) patients.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021089

(Optional Format 3-10-98)